

MAR - 7 2001

K003550

510(k) Notification

INFINITY etCO2 + Respiratory Mechanics Pod

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: November 16, 2000

2. Trade Name, Common Name and Classification Name:

A. Trade Name:

INFINITY etCO2 + Respiratory Mechanics (Flow) Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Spirometer, Monitoring (w/wo Alarm)	BZK	II	868.1850
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	CCK	II	868.1400

3. Predicate Device Identification:

INFINITIY etCO2 Pod
510(k) K992116

Novametrix CO2SMO Plus
510(k) K963380

4. Device Description:

The new INFINITY etCO2 pod + Respiratory Mechanics reuses the hardware and software of the INFINITY etCO2 pod [510(k) K992116]. Modifications have been implemented to enable the Respiratory Mechanics functionality.

When used in conjunction with an INFINITY modular monitor (SC 7000 / SC 8000 / SC 9000XL) visual and audible alarms and alarm recordings for end-tidal CO2, inspired CO2, respiratory rate, peak inspiratory pressure, positive end-expiratory pressure and expired minute ventilation will be produced if any of these parameters exceed preset limits.

5. Intended Use:

When used in conjunction with an INFINITY modular monitor (SC 7000, SC 8000, SC 9000XL), the INFINITY etCO2 + Respiratory Mechanics Pod is intended to provide spirometric and carbon dioxide monitoring.

COMPANY CONFIDENTIAL

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6. Table of Device Similarities and differences to predicate device

	Predicate Device	Predicate Device	Applicant	Explanation of Differences
Manufacturer	Novamatrix Medical Systems CO2SMO Plus	Siemens Medical Systems INFINITY etCO2 Pod	Siemens Medical Systems INFINITY etCO2 + Respiratory Mechanics Pod	
510(k) Number	K963380	K992116		
Intended Use	To provide spirometric, carbon dioxide and pulse oximetry monitoring	To provide carbon dioxide monitoring.	When used in conjunction with an INFINITY modular monitor (SC 7000, SC 8000, SC 9000XL), the INFINITY etCO2 + Respiratory Mechanics Pod is intended to provide spirometric and carbon dioxide monitoring.	The INFINITY etCO2 + Respiratory Mechanics Pod does not measure or display pulse oximetry
Intended Population	Adult/Pediatric/Neonatal	Same	Same	
Intended Environment	Operating and emergency rooms and intensive care units	Same	Same	
Measuring Capabilities				
Displayed parameters		EtCO2, iCO2, Respiration rate (RRc)	Same	
Display Scales		0-40, 0-60, 0-80, 0-100 mmHg	Same	
Measuring method		Dual-wavelength, non-dispersive infrared	Same	
Measuring capabilities		Mainstream and Sidestream	Mainstream only	The etCO2 + Resp. Mech. Pod has one pump, unlike the CO2SMO Plus that has two pumps. Therefore, to avoid contamination sidestream is disallowed.
Measuring range		0 to 100 mmHg CO2 partial pressure	Same	
Averaging		Breath, 10s, 20s, Instantaneous	Same	
Respiratory Mechanics	Flow Range (L/min)		Same	
	Volume (ml)		Same	
	CO2 (torr)		Same	
	Pressure (cm H2O)		Same	

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7. Assessment of non-clinical performance data for equivalence: Section S

8. Assessment of clinical performance data for equivalence: Section U

9. Biocompatibility:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances:

EN 864: 1996 Capnometers for use with Humans, Particular Requirements

EN 60601-1: 1990 with A1 and A12: 1993, A2: 1995 and A13: 1996 (IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995), Medical Electrical Equipment, Part 1: General Requirements for Safety.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K003550
Trade Name: INFINITY etCO2 + Respiratory Mechanics (Flow) Pod
Regulatory Class: II (two)
Product Code: CCK & BZK
Dated: February 9, 2001
Received: February 13, 2001

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

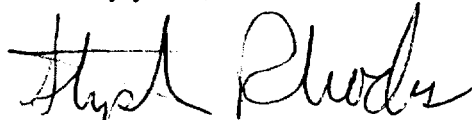
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is fluid and cursive, with the first name "James" and last name "Dillard" being the most prominent parts.

James E. Dillard III

Director

Division of Cardiovascular

and Respiratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K003550Device Name: Siemens INFINITY etCO2+ Respiratory Mechanics (Flow) PodIndications for Use:

Siemens INFINITY etCO2+ Respiratory Mechanics Pod is indicated for use in the adult, pediatric and neonatal populations, in an environment where patient care is provided by healthcare professionals, i.e. Physicians, Nurses, Technicians when the professional determines that the device is required to provide spirometric and carbon dioxide monitoring when used in conjunction with INFINITY modular monitors (SC 7000, SC 8000, SC 9000XL). Visual and audible alarms and alarm recordings for end-tidal CO2, inspired CO2, respiratory rate, peak inspiratory pressure, positive end-expiratory pressure and expired minute ventilation will be produced if any of these parameters exceed preset limits.

MRI Compatibility Statement:

The Siemens INFINITY etCO2+ Respiratory Mechanics Pod is not intended for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

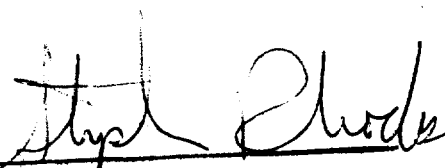
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K003550